PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Herron et al.

Serial No.: 09/839,778

Filed: April 20, 2001

For: DIAGNOSTIC DEVICE AND METHOD

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APPEAL BRIEF

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Attn: Board of Patent Appeals & Interferences

Sirs:

This Appeal Brief is being submitted in triplicate and in the format of 37 C.F.R. § 1.192(c). A check in the amount of $330.00 for the fee under 37 C.F.R § 1.17(c) for filing a brief in support of an appeal is enclosed.

(1) REAL PARTY IN INTEREST

The real party in interest in the above-referenced appeal is BioCentrex, LLC, which has received an exclusive license to the technology disclosed and claimed in the above-referenced application from the University of Utah Research Foundation, the named assignee of the above-referenced application, as evidenced by the assignments that have been recorded with the U.S. Patent & Trademark Office at Reel 009243, Frame 0029, on June 8, 1998, and at Reel 009712, Frame 010729, on January 19, 1999.

(2) RELATED APPEALS AND INTERFERENCES

Appellants are not aware of any related applications that are currently on appeal or the subject interference proceedings that would affect the outcome of this appeal.

(3) STATUS OF THE CLAIMS

Claims 1-21 are currently pending and under consideration in the above-referenced application.

Each of claims 1-21 stands rejected.

The rejections of claims 1-21 are being appealed.

(4) STATUS OF AMENDMENTS

The above-referenced application, U.S. Patent application serial no. 09/839,778 (hereinafter "the '778 Application"), was filed on April 20, 2001, as a divisional of the U.S.

Patent application serial no. 08/933,203, filed on September 18, 1997. The '778 Application was originally filed with 35 claims.

A Restriction Requirement was mailed on September 11, 2002. Claims 1-35 were subject to the Restriction Requirement.

On December 16, 2002, a Response to the Restriction Requirement was filed with a petition and the appropriate fee for a two-month extension of time. In that Response, an election was made to prosecute claims 1-21 without traverse.

In a Notice to Comply dated February 24, 2003, the Office required that a sequence listing be filed and that the specification be amended to identify all of the listed nucleic acid and peptide sequences.

On April 1, 2003, a Response to the Notice to Comply was filed. The Response indicated that there are no nucleic acid or peptide sequences in the above-referenced application and requested withdrawal of the demands that a sequence listing and amendments to the specification be filed.

A first Office Action on the merits of claims 1-21 was mailed by the Office on June 30, 2003. Each of claims 1-21 was rejected.

An Amendment was filed in response to the first Office Action on September 30, 2003. That Amendment included several claim revisions, as well as explanations of the patentability of claims 1-21.

On December 31, 2003, a Final Office Action followed. The rejections on the merits of claims 1-21 were maintained.

In an Amendment Under 37 C.F.R. § 1.116, another attempt was made to explain to the Examiner the reasons why claims 1-21 are patentable over the art of record. In addition, minor claim revisions were presented to correct formal errors therein.

The Examiner responded on June 4, 2004, with an Advisory Action. In the Advisory Action, she indicated that the previously proposed claim amendments would be entered, but continued to reject claims 1-21.

Accordingly, a Notice of Appeal was filed on June 30, 2004, with a petition and the appropriate fee for a three-month extension of time.

This Appeal Brief follows the Notice of Appeal, and is being filed within two months of the filing date thereof.

(5) SUMMARY OF THE INVENTION

The disclosure and claims of the above-referenced application are drawn to methods for performing assays. More specifically, these methods include so-called "kinetic assays" for more than one analyte. Paragraphs **[0094]** through **[0100]**.

Such a method includes substantially simultaneously evaluating the presence of a plurality of analytes in a sample. Paragraphs **[0115]** through **[0123]**; Figs. 16-21. At least one of the evaluated analytes is known to be associated with an acute metabolic state or disease state. *See, e.g.,* paragraph **[0092]**. The binding kinetics are then evaluated to substantially simultaneously determine concentrations of the analytes. Paragraphs **[0094]** through **[0100]** and **[0121]**. This determination continues until a reliable determination has been made of whether the at least one analyte is present in an amount which is indicative of the acute metabolic

state or disease state. Paragraphs **[0013]**, **[0099]**, **[0100]**. The results are then reported. Paragraph **[0100]**.

The method may be effected as a competition-type assay, a sandwich assay, or otherwise. Paragraph **[0087]**.

The use of waveguide assay techniques is particularly useful for obtaining real-time information on the binding kinetics and, thus, the amount of each analyte in a particular sample. Paragraph **[0011]**. When such techniques are used, light is internally reflected within the waveguide to generate an evanescent field at a surface of the waveguide. *See, e.g.,* paragraphs **[0046]**, **[0050]**, **[0075]**. When markers, such as fluorescent dyes, metal labels, or the like, that are used to measure the binding kinetics in the assay enter the evanescent field, they become "excited." *See, e.g.,* paragraphs **[0090]**, **[0091]**. The level of excitation may be measured to facilitate evaluation of the binding kinetics or the amount of a particular analyte in the sample. Paragraphs **[0095]** through **[0100]**.

By way of nonlimiting example, an assay according to the invention disclosed in the '778 Application may be used to evaluate the cardiac health of an individual. Paragraphs **[0116]** through **[0123]**. In such an assay, the presence of a combination of cardiac markers, such as troponin, creatine-kinase, myoglobin, or the like, may be evaluated and considered in quickly (*e.g.,* within a matter of minutes) diagnosing the individual's cardiac health. *Id.; see also,* **[0010]** through **[0014]**.

(6) ISSUE

Whether claims 1-21 are allowable under 35 U.S.C. § 102(e) for being directed to subject matter which is novel over the subject matter described in U.S. Patent 5,747,274 to Jackowski (hereinafter "Jackowski").

(7) GROUPING OF CLAIMS

Claims 1-21 should be grouped together. Independent claim 1 is the most generic claim of this group. While each of claims 2-21 stands with claim 1, claims 2, 7, 8, 10, and 12 do not fall with claim 1 for the reasons that are set forth in the ensuing ARGUMENT section of this Appeal Brief.

(8) ARGUMENT

Claims 1-21 stand rejected under 35 U.S.C. § 102(e) for being directed to subject matter which is allegedly anticipated by the subject matter disclosed in Jackowski.

(A) LEGAL AUTHORITY

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference which qualifies as prior art under 35 U.S.C. § 102. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Notably, patent applicants are their own lexicographers and, thus, determine the meanings of the various terms that appear in the claims of their patent applications. M.P.E.P. § 2173.01. In this regard, the meaning of every term in a claim should be determined from the descriptive portion of the specification. M.P.E.P. § 608.01(o). "When the specification states the meaning that a term is intended to have, the claim is examined using that meaning . . ." M.P.E.P. § 2173.05(a), citing *In re Zletz,* 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989).

(B) REFERENCE RELIED UPON

Jackowski describes that multiple assays for different analytes may be conducted on a single sample that is obtained at a single point in time. Col. 22, lines 12-14. Thus, the amounts of markers that are simultaneously present in the sample may be accurately determined. Col. 22, lines 15-19. Assays for each of the analytes of interest may then be performed within a given time frame after the sample is obtained. Col. 22, lines 7-8.

As used in Jackowski, the term "simultaneous" does not have its ordinary meaning or that used in the specification of the above-referenced application. Rather, as indicated at col. 22, lines 2-19, the term "simultaneous" is not used in Jackowski to indicate that analysis of different analytes occurs concurrently, but that the analysis occurs within a given period of time (*e.g.,* thirty minutes) and that each analysis is performed on part of the same sample.

The description of Jackowski is also limited to determinations that occur at different points in time that correspond to different assays conducted on different parts of a single sample, all of which are conducted within a give window of time. Col. 22, lines 2-19; *see also* col. 22, lines 2-12; col. 29, lines 50-63, col. 30, lines 18-26; col. 35, lines 60-68.

(C) ANALYSIS

Independent claim 1 of the '778 Application is directed to a method for performing an assay. The method of independent claim 1 includes, among other things, substantially simultaneously evaluating the presence of a plurality of analytes in a sample. At least one of the plurality of analytes has known parameters that are indicative of an acute metabolic or disease state. In addition, the method of independent claim 1 includes substantially simultaneously determining concentrations of each of the plurality of analytes in the sample. The substantially simultaneous determination is continued until at least one of the analytes has been reliably determined to be present in an amount that is indicative of a metabolic or disease state. Once the amount of at least one of the analytes has been reliably determined, that determination is reported.

In contrasting the subject matter recited in independent claim 1 to that described in Jackowski, it is apparent that Jackowski does not anticipate several elements of independent claim 1, as would be required to maintain the 35 U.S.C. § 102(e) rejection of independent claim 1.

First, it is respectfully submitted that Jackowski does not expressly or inherently describe that multiple analytes of a sample may be substantially simultaneously evaluated. The meaning of the term "simultaneously," as used in independent claim 1, should be determined from the specification of the '778 Application rather than from the meaning that Jackowski has supplied for that term. *See* M.P.E.P. §§ 608.01(o); 2173.01; and 2173.05(a). The specification of the above-referenced application, at paragraphs **[0072]**, **[0078]**, and, in particular, **[0121]**, makes it

extremely clear that when two or more analytes in a sample are evaluated substantially simulataneously, they are evaluated at substantially the same time, or substantially concurrently. Jackowski, in contrast, clearly indicates that different analytes in a sample need not be evaluated concurrently. Col. 22, lines 6-12. Therefore, Jackowski does not anticipate the element of "substantially simultaneously evaluating the presence of a plurality of analytes in a sample" recited in independent claim 1.

Second, for the same reasons Jackowski does not expressly or inherently describe, or anticipate, "substantially simultaneously evaluating . . .," it is respectfully submitted that Jackowski does not expressly or inherently describe, or anticipate, "substantially simultaneously determining concentrations of each of the plurality of analytes in the sample," as is required by independent claim 1.

Third, it is respectfully submitted that Jackowski neither expressly nor inherently describes "*continuing* a substantially simultaneous determination" of the presence of at least one analyte in a sample "*until* the at least one analyte has been reliably determined to be present in an amount indicative of a metabolic or disease state . . ." (emphasis supplied). The term "continuing" clearly indicates that the determination of that at least one analyte is effected over a period of time, rather than at a single point in time. The description of Jackowski is, however, limited to determining the amount of each analyte in a sample at a single point in time. Therefore, Jackowski does not anticipate "continuing [a] substantially simultaneous determination until . . . at least one analyte has been reliably determined to be present in an amount indicative of [a] metabolic or disease state . . ."

In view of the foregoing, it is respectfully submitted that, under 35 U.S.C. § 102(e), independent claim 1 recites subject matter which is allowable over that described in Jackowski.

Each of claims 2-21 is allowable, among other reasons, for depending either directly or indirectly from claim 1, which is allowable.

Claim 2 is additionally allowable because Jackowski includes no express or inherent description that "evaluating the presence of at least one other analyte in [a] sample" may *continue* after a report of a reliable determination that at least one analyte in the sample is present in an amount which is indicative of a metabolic or disease state. Again, the description of Jackowski is limited to effecting evaluations of the presence of analytes in a sample at single points in time rather than continuously.

Claim 7 is further allowable since Jackowski neither expressly nor inherently describes "correlating a rate of reaction between . . . at least one analyte and [a] corresponding reactive element to a concentration of the at least one analyte."

Claim 8 is also allowable because Jackowski does not expressly or inherently describe that a substantially simultaneous determination of the presence of at least one analyte in a sample may be effected by reacting at least one analyte in a sample with a corresponding reactive element, the corresponding reactive element being one of a plurality of reactive elements that are arranged in one or more patterns on the surface of a waveguide.

Claim 10 is additionally allowable since Jackowski lacks any express or inherent description of stimulating a light signal from a reactive element, which is indicative of a rate of reaction between the analyte of interest and the type of reactive element from which the light signal is stimulated.

Claim 12 depends from claim 10 and is further allowable because there is no express or inherent description in Jackowski of correlating a rate of reaction between at least one analyte and a corresponding reactive element to a concentration of the at least one analyte.

For these reasons, reversal of the 35 U.S.C. § 102(e) rejections of claims 1-21 is respectfully requested.

(9) APPENDIX

Claims 1-21 are attached as the APPENDIX to this Appeal Brief.

(10) CONCLUSION

It is respectfully submitted that the subject matter to which claims 1-21 are directed is not anticipated under 35 U.S.C. § 102(e) by the disclosure of Jackowski. Accordingly it is respectfully requested that the 35 U.S.C. § 102(e) rejections of claims 1-21 be reversed and that each of these claims be allowed.

Respectfully submitted,

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APPENDIX

CLAIMS

1. (original) A method for performing an assay, comprising:

substantially simultaneously evaluating the presence of a plurality of analytes in a sample, at least one analyte of the plurality of analytes having known parameters indicative of an acute metabolic or disease state;

substantially simultaneously determining concentrations of each of the plurality of analytes in the sample;

continuing the substantially simultaneous determination until the at least one analyte has been reliably determined to be present in an amount indicative of the metabolic or disease state; and

reporting said reliable determination of the presence of the plurality of analytes in an amount indicative of the metabolic or disease state.

2. (previously presented) The method according to claim 1, wherein evaluating the presence of at least one other analyte in the sample continues after the report of the reliable determination of an amount indicative of the acute metabolic or disease state in order to accurately determine the presence or concentration of the at least one other analyte.

3. (original) The method according to claim 1, comprising evaluating binding of the plurality of analytes to corresponding reactive elements over a plurality of time points.

4. (original) The method according to claim 1, wherein the substantially simultaneous determination is effected by reacting at least one analyte of the plurality of analytes with a corresponding reactive element.

5. (original) The method according to claim 4, wherein the substantially simultaneous determination includes exposing the sample to the reactive elements corresponding to each analyte of the plurality of analytes.

6. (original) The method according to claim 5, wherein each reactive element is substantially immobilized on a waveguide surface.

7. (original) The method according to claim 4, wherein the continuation of the substantially simultaneous determination includes correlating a rate of reaction between the at least one analyte and the corresponding reactive element to a concentration of the at least one analyte.

8. (Currently amended) The method according to claim ~~7~~4, wherein the reactive elements are arranged in one or more patterns on ~~the~~ a waveguide surface.

9. (original) The method according to claim 4, wherein the substantially simultaneous determination includes introducing a light beam including at least one wavelength appropriate for

stimulating a light signal from the corresponding reactive element when the corresponding reactive element has coupled with the at least one analyte.

10. (original) The method according to claim 9, wherein the light signal is indicative of a rate of reaction between the analyte of interest and the corresponding reactive element.

11. (original) The method according to claim 10, wherein the substantially simultaneous determination includes measuring the light signal generated from the reaction of the at least one analyte with the corresponding reactive element.

12. (original) The method according to claim 10, wherein the continuation of the substantially simultaneous determination includes correlating a rate of reaction between the at least one analyte and the corresponding reactive element to a concentration of the at least one analyte.

13. (original) The method according to claim 1, wherein the at least one analyte is a marker released from cardiac tissue only after a myocardial infarction.

14. (original) The method according to claim 13, wherein the marker comprises myoglobin.

15. (original) The method according to claim 1, wherein the at least one analyte is a cardiac specific marker.

16. (original) The method according to claim 15, wherein the at least one analyte comprises troponin.

17. (original) The method according to claim 16, wherein the troponin comprises individual troponin subunits.

18. (original) The method according to claim 16, wherein the troponin comprises a complex including at least one troponin subunit.

19. (original) The method according to claim 16, wherein the troponin comprises at least one of native troponin and a modified troponin.

20. (original) The method according to claim 15, wherein the at least one analyte comprises creatine kinase.

21. (original) The method according to claim 20, wherein the creatine kinase comprises CK-MB.

22-35. (canceled)

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/839,778
Filing Date	April 20, 2001
First Named Inventor	Herron et al.
Group Art Unit	1641
Examiner Name	G. Gabel
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ENCLOSURES *(check all that apply)*

- ☒ Postcard receipt acknowledgment (attached to the front of this transmittal)
- ☒ Duplicate copy of this transmittal sheet in the event that additional filing fees are required under 37 C.F.R. § 1.16
- ☐ Preliminary Amendment
- ☐ Response to Restriction Requirement/Election of Species Requirement dated
- ☐ Amendment in response to office action dated
- ☐ Amendment under 37 C.F.R. § 1.116 in response to final office action dated
- ☐ Additional claims fee - Check No. in the amount of $
- ☐ Letter to Chief Draftsman and copy of FIGS. with changes made in red
- ☐ Transmittal of Formal Drawings
- ☐ Formal Drawings (sheets)
- ☐ Information Disclosure Statement, PTO/SB/08A; ☐ copy of cited references
- ☐ Supplemental Information Disclosure Statement; PTO/SB/08A; copy of cited references and Check No. in the amount of $180.00
- ☐ Associate Power of Attorney
- ☐ Petition for Extension of Time and Check No. in the amount of $
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- ☐ Fee Transmittal Form
- ☐ Certified Copy of Priority Document(s)
- ☐ Assignment Papers *(for an Application)*
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Remarks

The Commissioner is authorized to charge any additional fees required but not submitted with any document or request requiring fee payment under 37 C.F.R. §§ 1.16 and 1.17 to Deposit Account 20-1469 during pendency of this application.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm *or* Individual name	Brick G. Power Registration No. 38,581
Signature	
Date	August 30, 2004

CERTIFICATE OF MAILING

Express Mail Label Number: EV348043025US

Date of Deposit: August 30, 2004

Person Making Deposit: Christopher Haughton